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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,142	06/26/2006	Tadayuki Tokunaga	292949US0PCT	5697

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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.  
1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER
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MAEWALL, SNIGDHA

ART UNIT	PAPER NUMBER
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1612

NOTIFICATION DATE	DELIVERY MODE
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11/24/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/584,142	<b>Applicant(s)</b> TOKUNAGA ET AL.	
	<b>Examiner</b> Snigdha Maewall	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/26/06 and 09/05/06</u> .                                   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Summary**

1. Receipt of IDS filed on 06/26/06 and 09/05/06 is acknowledged.

### ***Restriction/Election***

Applicant's election with traverse of Group I, claims 1-3 in the reply filed on 09/02/09 is acknowledged. The traversal is on the ground(s) that no search burden will be imposed on the Examiner; this is not found persuasive because claim 4 is drawn to method claims and the search that will be performed for composition claims will not also anticipate or render the method of stabilizing a composition comprising calcium and monofluorophosphate ions in a certain amount. The Examiner agrees with Applicants to extend the search to the process claim once the composition claim is found allowable.

The requirement is still deemed proper and is therefore made FINAL.

Claim 4 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 09/02/09.

Accordingly, claims **1-3** are under prosecution.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35

U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being

anticipated by Lee et al. (USP 6,214,321).

'321 teaches remineralization of teeth comprising calcium salt such as calcium phosphate and (calcium glycerophosphate) salts from amounts ranging from 0.01% to 30%, preferably from 0.1% to 20%, see title, column, 3 lines 10-15 and 30-32. The reference teaches pH due to acidic environment of first composition to be less than 7 preferably from 1 to 6.5, see column 3, lines 35-39. The second composition comprises monofluorophosphate such as sodium and stannous and sodium fluoride which provides fluoride ions from about 25 to 5000 ppm of fluoride ions, see column 3, lines 53-55. The composition can be in the form of tooth paste, gel, powder or mouth wash, see column 3, lines 62-64. The first composition has lactic or malic acid or acid

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salts may also be applied. See column 4, lines 12-14. Humectants such as sorbitol, mannitol and maltitol are disclosed in column 4, lines 26-33. Prior art does not teach the instantly claimed calcium ions from 100 to 16000 ppm, however, the reference teaches the amount of calcium supplying compounds to be from 0.1% to 20% as discussed above, since the instant specification uses 1% of calcium ion supplying compound in Table 1 on page 12, it is the position of the Examiner that prior art's range of calcium ion supplying compound that is from 0.1% to 20% will supply the claimed amount of calcium ions that is from 100 to 16000 ppm absent evidence to contrary. (It is to be noted that it is known in the dental art for remineralization that monofluorophosphate supplies monofluorophosphate ion first and then fluoride ion, it is the fluoride ion that is measured to check the concentration in ppm for monofluorophosphate compounds, USP PG pub. 20060099153, see paragraph [0021] and US PG pub. 20030170185, see examples 31-32 under ingredients under sodium monofluorophosphate, the concentration in terms of fluoride ion is 950 ppm.)

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over

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Winston et al. (USP 6,036,944) in view of Lee et al. (USP 6,214,321).

'944 teach process for the remineralization and mineralization of teeth, title and abstract. The water soluble calcium compounds in compositions are calcium glycerophosphate, calcium chloride etc which provides at least about 100 ppm and preferably from 100 ppm to upper limit of 35, 000 ppm of calcium ions, see column 7, lines 44-54. Suitable alkali metal monofluorophosphates are sodium monofluorophosphates, potassium monofluorophosphate, see column 9, lines 7-9. Humectants such as sorbitol are disclosed in column 10, lines 6-9 and pH is disclosed to be from 4.5 to about 7 in column 9, lines 32-34.

The reference does not teach the amount of monofluorophosphate ions released from composition and an acid such as malic or tartaric acid.

'321 teaches remineralization of teeth comprising calcium salt such as calcium phosphate and (calcium glycerophosphate) salts from amounts ranging from 0.01% to 30%, preferably from 0.1% to 20%, see title, column, 3 lines 10-15 and 30-32. The reference teaches pH due to acidic environment of first composition to be less than 7, preferably from 1 to 6.5, see column 3, lines 35-39. The second composition comprises monofluorophosphate such as sodium and stannous and sodium fluoride which provides fluoride ions from about 25 to 5000 ppm of fluoride ions, see column 3, lines 53-55. The composition can be in the form of tooth paste, gel, powder or mouth wash, see column 3, lines 62-64. The first composition has lactic or malic acid or acid salts may also be applied. See column 4, lines 12-14. Humectants such as sorbitol, mannitol and maltitol are disclosed in column 4, lines 26-33.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate monofluorophosphate providing fluoride ions in the range of 250 to 25000 ppm as disclosed by Lee et al. and it would have been obvious to one of ordinary skill to utilize malic or lactic acid to adjust pH of the composition of Winston et al. motivated by the teachings of Lee et al. One would have been motivated to combine the teachings of Lee et al. and Winston et al. because both the compositions are drawn to dental remineralization compositions.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

6. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over (USP 6,372,198) in view of Lee et al. (USP 6,214,321).

'198 teaches dentifrice for mineralization and remineralization of teeth, title, The composition comprises sodium mono fluorophosphates which provides 1000-1670 ppm (0.1 to 0.16% weight) of fluorine and calcium glycerophosphate provides 18 mol/L to 1.5 mol/L of calcium ions. Sorbitol is disclosed in example.

The reference does not teach acid or acid salts.

'321 teaches remineralization of teeth comprising calcium salt such as calcium

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phosphate and (calcium glycerophosphate) salts from amounts ranging from 0.01% to 30%, preferably from 0.1% to 20%, see title, column, 3 lines 10-15 and 30-32. The reference teaches pH due to acidic environment of first composition to be less than 7 preferably from 1 to 6.5, see column 3, lines 35-39. The second composition comprises monofluorophosphate such as sodium and stannous and sodium fluoride which provides fluoride ions from about 25 to 5000 ppm of fluoride ions, see column 3, lines 53-55. The composition can be in the form of tooth paste, gel, powder or mouth wash, see column 3, lines 62-64. The first composition has lactic or malic acid or acid salts may also be applied. See column 4, lines 12-14. Humectants such as sorbitol, mannitol and maltitol are disclosed in column 4, lines 26-33.

It would have been obvious to one of ordinary to utilize malic or lactic acid to adjust pH of the composition of '198 motivated by the teachings of Lee et al. One would have been motivated to combine the teachings of Lee et al. and Winston et al. because both the compositions are drawn to dental remineralization compositions.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-



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272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/  
Examiner, Art Unit 1612  
/Gollamudi S Kishore/  
Primary Examiner, Art Unit 1612